

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Emil D. KAKKIS

Application No.: 09/993,241

Filed: November 13, 2001

For: **METHODS FOR TREATING DISEASES  
CAUSED BY DEFICIENCIES OF  
RECOMBINANT  $\alpha$ -L-IDURONIDASE**

Art Unit: 1652

Examiner: Manjunath N. Rao

Confirmation No.: 8479

Attorney Docket No: 00800.0051.CNUS03

**RESPONSE TO RESTRICTION REQUIREMENT****RECEIVED**

APR 23 2003

TECH CENTER 1600/2900

Commissioner for Patents  
Washington, D.C. 20231

Sir:

This is in response to the Office Action dated **April 10, 2003**, and is submitted on or before the due date of **May 10, 2003**. Applicant believes that there is no fee associated with the submission of this matter. However, if there is a fee deficiency, the U.S. Patent and Trademark Office is authorized to charge the fee to Deposit Account No 08-3038.

**THE REMARKS**

The Examiner has required restriction to one of the following inventions pursuant to 35 U.S.C. §121:

I. Claims 1-13, drawn to formulation/pharmaceutical composition comprising human recombinant  $\alpha$ -L-iduronidase or biologically active fragments or mutein thereof with a purity of greater than 99%, classified in class 435, subclass 201.

II. Claims 14-57, drawn to a method of treating diseases caused all or in part by a deficiency of  $\alpha$ -L-iduronidase comprising administering the pharmaceutical composition comprising human recombinant  $\alpha$ -L-iduronidase or biologically active fragments or mutein thereof with a purity of greater than 99%, classified in class 424, subclass 94.1.